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10/760,488	01/21/2004	Hiroyuki Suzuki	KAS-197	9791

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EXAMINER

WRIGHT, PATRICIA KATHRYN

ART UNIT	PAPER NUMBER
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1797

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/760,488

Applicant(s)

SUZUKI ET AL.

Examiner

P. KATHRYN WRIGHT

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 November 2007 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Claims

1. This action is in response to papers filed November 21, 2007 in which claims 1-8 were canceled and claims 9-22 were added. The amendments have been thoroughly reviewed and entered.

Any objection/rejection not repeated herein has been withdrawn by the Examiner. New grounds for rejection, necessitated by the amendments, are discussed.

Claims 9-22 are under prosecution.

Drawings

2. The drawings are again objected to under 37 CFR 1.83(a) because they fail to show a "sample supply unit" or "sample buffer arrangement" in claim 9.

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "31" has been used to designate both a "second buffer unit" and "independent lines"; reference character "32" has been used to designate both a "second buffer" and "second buffer unit entrance"; reference character "33" has been used to designate both a "second buffer unit" and "third line switching unit", see amended paragraph beginning at page 16, line 25.

Similarly, reference character "34" has been used to designate both a "second buffer unit" and "line"; reference character "35" has been used to designate both a "second buffer unit" and "line entrance"; reference character "36" has been used to

designate both a "second buffer unit" and "sample rack delivery exits", see amended paragraph beginning at page 16, line 25.

4. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

5. The specification is again objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: "sample supply unit" in new claim 9. While Applicant has defined the "sample supply unit" as corresponding to "sample loading unit 3" and "urgent sample loading unit 5", this is not set forth in the specification or the claims as originally filed. Nor does the specification recite a "sample buffer arrangement...comprising at least two buffers".

Claim Objections

6. Claims 14-22 are objected to because of the following informalities: the preamble of claims 14-22 should clearly reference the claim from which it depends, for consistency with claims 1-13. For example, claims 14 should read "An automatic analyzer according to claim 9...". Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 9-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

New independent claim 9 recites a "sample supply unit". Applicant states in the REMARKS/ARGUMENTS section of the Reply, filed November 21, 2007, that the "sample supply unit" corresponds to "sample loading unit 3" and "urgent sample loading unit 5". However, new claim 10 recites a separate "urgent sample loading unit". Thus, it appears that Applicant is reciting the same limitation twice. The recitation of the same element under different names in different parts of the claim or the use of same term to refer to different elements is indefinite. The same term should be used for an element each and every time it is recited.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. New claims 9-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Mimura (US Patent No. 6,080,364), hereinafter "Mimura".

Mimura teaches an automatic analyzer system comprising a plurality of analytical modules 3a-g for analyzing a living body sample. The system includes a sample supply unit 17 for supplying samples to the sample buffer, and sample collection unit 18 for collecting samples from the sample buffer (see col. 4, line 4- col. 10, line 55).

The Mimura analyzer system includes a conveyer unit 20, 25 for conveying sample racks 1 to the analytical modules and conveying sample racks, for which sampling has completed, from the analytical module.

Please note that the "wherein clause" of claim 9 and claims 11-13 which functionally describes the operation of the conveyer unit has not received patentable weight. No means for moving the conveyer unit has been positively recited. Only structural language is determinative of the metes and bounds of an apparatus claim. Functional recitations, standing alone, while perhaps helpful in understanding the meaning of a claim and the invention that it represents, cannot be relied upon to distinguish over the prior art. Applicant must establish that what is expressly taught by the prior art does not inherently function in the manner required by the claim. Applicant

is reminded that a recitation of function may not distinguish over the prior art reference since an apparatus claim covers what a device is, not what it does.

Mimura also teaches a first buffer 70 disposed at one end of the conveying unit for receiving samples from the sample supply unit and a second buffer 22 disposed at the opposite end of the conveying unit and capable of holding samples for which sampling has completed, returning samples to be reanalyzed to the analytical modules, and returning samples to be reanalyzed to the sample collection unit (see Fig. 1).

Regarding claim 10, the "urgent sample loading unit" has been treated by the Examiner as the same element as the "sample supply unit 17" since Applicant has defined the inventive "sample supply unit" as corresponding to the "urgent sample loading unit".

Furthermore, Mimura teaches a controller 40. Please note that any method step performed by the controller, such as, controlling the analytical module to complete sampling of general samples currently being subjected to sampling, and controlling the conveyer unit to convey general samples still to be subjected to sampling to the first buffer when an urgent sample is loaded into the urgent sample loading unit has been analyzed is not attributed patentable weight in the context of a claim addressed to physical hardware. Such method steps are only an intended usage of the hardware, not a limitation of the hardware itself. Nevertheless, the controller Mimura is capable of controlling the analytical module to complete sampling of general samples currently being subjected to sampling, and controlling the conveyer unit to convey general samples still to be subjected to sampling to the first buffer 70 when an urgent sample is

loaded into the urgent sample loading unit. The controller also acts to convey the urgent sample to the analytical module and to convey general samples in the first buffer to the analytical module after said urgent sample has been analyzed (see for example col. 4, line 18-col. 6, line 39).

Regarding claims 14-18, the first sample buffer 70 (part of the sample buffer arrangement) of Mimura has a structure (openings) for holding a plurality of sample racks substantially spokewise on a base (rotor) rotatable on an axis (see col. 4, lines 49+.)

With respect to claims 19-22, the second sample buffer 22 of Mimura has a structure for holding a plurality of the sample racks side-by-side substantially in one direction, wherein the buffer structure includes a mechanism for moving the base in a direction perpendicular to the direction in which the sample racks are arranged (claim 8), see Fig. 1.

11. New claims 9-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Takahashi et al. (US Patent No. 6,290,907), hereinafter "Takahashi".

Takahashi teaches an automatic analyzer system comprising a plurality of analytical modules 3, 5-9 for analyzing a living body sample. Takahashi teaches sample buffer arrangement comprising a plurality of buffers 2a,b, 13, 14 capable of holding a plurality of sample containers containing samples and supplying desired ones of the sample containers held on the sample buffer to the conveyer unit, and receiving the

sample containers returned from the analytical module through the conveyer unit. The buffers 2a, b and 14 are disposed on ends of conveyor units (see Fig. 1).

Takahashi also teaches a sample supply unit 50 (includes urgent sample loading unit of claim 10) for supplying samples to the sample buffer, and sample collection unit 60 for collecting samples from the sample buffer (see col. 8, lines 37+).

The analyzer system of Takahashi includes a conveyer unit 1 for conveying sample racks 10 to the analytical module and conveying sample racks, for which sampling has completed, from the analytical module. Takahashi the conveyer unit includes two conveyor lines (a main transportation line and a feedback transportation line), see col. 4, lines 18-40.

Note that the "wherein clause" of claim 9 and claims 11-13 which functionally describes the operation of the conveyer unit has not received patentable weight. No means for moving the conveyer units back and forth has been positively recited in claims 9 and 11-13. Only structural language is determinative of the metes and bounds of an apparatus claim. Functional recitations, standing alone, while perhaps helpful in understanding the meaning of a claim and the invention that it represents, cannot be relied upon to distinguish over the prior art. Applicant must establish that what is expressly taught by the prior art does not inherently function in the manner required by the claim. Since no means for moving the conveyer units back and forth has been positively recited in claims 9 and 11-13, the claims fail to distinguish over the prior art reference since an apparatus claim covers what a device is, not what it does.

Regarding claim 10, the "urgent sample loading unit" has been treated by the Examiner as the same element as the "sample supply unit 50" since Applicant has defined the inventive "sample supply unit" as corresponding to the "urgent sample loading unit". However, please note that Takahashi does teach a separate urgent sample loading unit 12 (see col. 5, lines 44-47).

Furthermore, Takahashi teaches a controller 17. Please note that any method step performed by the controller, such as, controlling the analytical module to complete sampling of general samples currently being subjected to sampling, and controlling the conveyer unit to convey general samples still to be subjected to sampling to the first buffer when an urgent sample is loaded into the urgent sample loading unit has been analyzed is not attributed patentable weight in the context of a claim addressed to physical hardware. Such method steps are only an intended usage of the hardware, not a limitation of the hardware itself. Nevertheless, the controller 17 of Takahashi does control the analytical module to complete sampling of general samples currently being subjected to sampling, and controlling the conveyer unit to convey general samples still to be subjected to sampling to the first buffer when an urgent sample is loaded into the urgent sample loading unit. The controller also acts to convey the urgent sample to the analytical module and to convey general samples in the first buffer to the analytical module after said urgent sample has been analyzed (see for example col. 5, line 40-col. 6, line 23 and col. 8, et seq.)

Response to Arguments

12. Applicant's arguments filed November 21, 2007 have been fully considered but they are not persuasive.

With respect to the previous objection to the drawings and specification in which the "sample supply unit" is not shown, Applicant argues that the "sample supply unit" corresponds to the "sample loading unit 3" and the "urgent sample loading unit 5", as allegedly shown in Figure 1.

The Examiner does not agree that this limitation is adequately shown in the figures, since this relationship was not set forth in the specification or the claims as originally filed. In fact, as pointed out above, new claim 10 recites a separate "urgent sample loading unit". Thus, it is unclear whether Applicant is reciting the same limitation twice using a different name (sample loading unit and urgent loading unit). Furthermore, any attempt include the recitation that the that the "sample supply unit" corresponds to the "sample loading unit 3 and the urgent sample loading unit 5" into the specification and/or claims will be considered new matter by the Examiner since this limitation does not appear to be supported in the specification or figures as originally filed.

Regarding the previous rejection of claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Mimura (US Patent No. 6,080,364), Applicant argues that Mimura does not disclose or suggest providing a downstream buffer in connection with evacuation of a conveyor line to make room for analysis of an urgent sample.

The Examiner does not agree since Mimura meets all the structural limitation of the new apparatus claim 9. That is, Mimura teaches a first buffer 70 disposed at one end of a conveying unit 20, 25 for receiving samples from the sample supply unit 17 and a second buffer 22 disposed at the opposite end of the conveying unit and capable of holding samples for which sampling has completed, returning samples to be reanalyzed to the analytical modules, and returning samples to be reanalyzed to the sample collection unit (see Fig. 1). Both buffers 70 and 22 are in connection with the conveying units 20, 25, see Fig. 1. Functional language describing the operation of the conveyor and controller has not received patentable weight in the instant apparatus claims.

With respect to the previous rejection of claims 1-6 and 8 under 35 U.S.C. 102(b) as being anticipated by Takahashi (US Patent No. 6,290,907), Applicant argues that the buffers of 2a and 2b receive and return the sample racks in a "first in -first out" manner.

The Examiner does not agree that this is germane to the argument since nothing in the claims precludes the buffers from receiving and returning the sample racks in a "first in -first out" manner. Again, functional language describing the operation of the conveyor and controller has not received patentable weight in the instant apparatus claims.

Conclusion

13. No claims allowed.
14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Wright whose telephone number is 571-272-2374. The examiner can normally be reached on Monday thru Thursday, 9 AM to 6 PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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pkw

/Jill A. Warden/
Supervisory Patent Examiner, Art Unit 1797